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Patent Application
Attorney Docket No. PC10270B

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(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Leah E. Appel, et al. :

Examiner: Susan T. Tran

APPLICATION NO.: 10/799,536 :

FILING DATE: March 11, 2004

: Group Art Unit: 1615

TITLE: Controlled Release By Extrusion of Solid :
Amorphous Dispersions of Drugs

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Response And Amendment Under Rule 111

This is in response to the Office Action mailed on February 2, 2005 in the above-identified application. Reconsideration and allowance are respectfully requested in light of the amendments and comments herein.

Claims 49-78 are currently in the application.

Claims 49-62 were objected to because of the word "and" in line 5.

Applicants have changed "and" to "or", as required by the Examiner. Although the rejection was made in respect of claims 49-62 only, the same change has been made to claim 63 for consistency.

Claims 66-68 and 71 were rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The Examiner contended that Applicants' specification does not provide support for the limitation "meltable excipient" recited in claims 66 and 67.

Reconsideration and withdrawal of the rejection are respectfully requested on the basis that Applicants' specification clearly provides support for "meltable excipient". For example, at page 16 it is stated

The amorphous solid dispersion of drug may be prepared by any of the known ways mentioned above, including, for example, by melt fusion, by mechanical processing such as in a twin-screw extruder or in a ball mill, or by solvent processing. [Page 16, lines 27-31]